The examiner now rejects claims 1 and 3 as encompassing "new matter" in light of the previously submitted amendment. Specifically, the examiner argues that the term "not more than 50 residues" is not found in the application. Applicant traverse the rejection, but have amended to the claims to remove this recitation. In its place, a clarifying amendment has been provided. That amendment specifies the size of the peptide to be 12-37 residues, which limitation derives directly from the smallest and largest peptides disclosed in applicants' sequence listing. The creation a particular range from examples is appropriate, even though the application does not recite the particular range, where it is clear to those of skill in the art that the specification describes that which is claimed. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In support of this limitation, applicants include the declaration of Andrew D. Robertson, which provides evidence that one of skill in the art would find the amended claims supported by the application as filed.

The amendment is believed to obviate any "new matter" concerns. Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

III. Rejections Under 35 U.S.C. §102

A. Mahoney et al.

Claims 1 and 3 are rejected as lacking novelty over Mahoney *et al.*, which is said to disclose, embedded within a much larger polypeptide, the amino acid sequence of SEQ ID NO:27. In the previous response, applicants traversed the anticipation rejection on the ground that Mahoney *et al.* discloses polypeptides of at least 152 residues, whereas the present invention claims much shorter peptides. Applicants once again traverse the rejection.

The examiner's response to applicants' position is as follows. First, it is argued that the rejection is proper as "the prior art anticipates the claimed invention by disclosing a cathelin-related protein 2 # status predicted residues 124-152 (not more than 50 residues) with the same or similar characteristics as claimed." Second, the examiner argues that "the compositions of the prior art are believed to inherently possess properties which anticipates [*sic*] the claimed invention, or if they are not the same, the compositions ... would nonetheless render the claims obvious because it possesses [*sic*] similar characteristics and functions [*sic*] in the same manner as claimed ...." These comments reflect a fatally flawed anticipation analysis, as discussed in detail below.

First, applicants wish to clarify if this is an anticipation rejection or not. Admittedly, §102 is cited, but the examiner seems so unconvinced that the cited art actually discloses ***the same subject matter*** that resort is made to "similar characteristics," sounding in terms of obviousness. So, before any further action is taken by the examiner, ***applicants specifically request that the examiner clarify whether this rejection is for anticipation or obviousness***, which require distinct legal analyses. Clearly, if the latter grounds for rejection is advanced, the Office Action is totally devoid of anything like a proper §103 analysis. Thus, the best that

applicants can do at this juncture is point out why the anticipation rejection is improper on its face, and traverse any putative obviousness rejection on the grounds that the elements of a *prima facie* case have not even been addressed.

Moving forward, applicants point out that the claimed invention is a peptide – a short series of amino acids linked by peptide bonds. In order for anticipation to stand, there must be a teaching in the prior art of each and every element of the claimed invention. Here, one such limitation is ***the upper size limit on the length of the peptide, now 37 residues***. As spelled out quite clearly in the previous response, the cited art discloses much longer proteinaceous molecules. Thus, an anticipation rejection clearly is improper.

The examiner, either knowingly or not, attempts to "fudge" this element by making a clear misstatement of fact – that Mahoney *et al.* actually discloses a discrete peptide of less 12 to 37 residues. However, the only thing the examiner points to is ***the PTO's manipulation of Mahoney's sequence*** in the form of a homology search. Applicants submit that it is both factually incorrect, and quite disingenuous, to cite Mahoney *et al.* for something it clearly does not disclose.

Finally, as pointed out previously, the situations presented by *In re Best* and *In re Fitzgerald*, legal precedent relied up by the examiner, are not applicable here. In both cases, ***compositions*** were being claimed in terms of ***functional*** characteristics, and the issue was whether the prior art ***methods*** inherently provided products with those same ***functional*** characteristics. Here, there is no functional claiming, and similarly no question that the composition of matter is distinct from the prior art in a ***structural*** sense – Mahoney *et al.* discloses polypeptides of at least 152 residues, whereas the present invention claims much shorter peptides. Thus, the legal precedent cited is inappropriate here.

If the examiner intends to maintain this rejection, it is respectfully requested that the examiner ***point to the precise location in Mahoney et al. where it discloses a peptide of 12-37 residues in length***. Assuming no such citation is forthcoming, reconsideration and withdrawal of the rejections is, therefore, respectfully requested.

B. Bagella et al.

Claims 1 and 3 are rejected as lacking novelty over Bagella *et al.*, which is said to disclose, embedded within a much larger polypeptide, the amino acid sequence of SEQ ID NO:27. Applicants once again traverse the rejection.

The basis for this rejection is precisely the same as that discussed above with respect to Mahoney *et al.* Not surprisingly, it is defective for the same reasons. In summary, Bagella *et al.* fails to teach a relevant ***peptide of 12-37 residues in length***. In the absence of such a teaching, it is a legal impossibility for Bagella *et al.* to anticipate claims 1 and 3. Reconsideration and withdrawal of the rejection is therefore requested.

C. Merluzzi et al.

Claims 1 and 3 are rejected as lacking novelty over Merluzzi *et al.*, which is said to disclose, embedded within a much larger polypeptide, the amino acid sequence of SEQ ID NO:27. The rejection differs from those preceding in that the examiner has also pointed to a disclosure of a 29-residue ovine cathelicidin designated SMAP29. Applicants traverse the rejection, but in the interest of advancing the prosecution, the sequence corresponding to SEQ ID NO:27 has been canceled from the claim. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

IV. New Claims 32-55

Applicants have new claims 32-55. In claims 32 and 33, the peptide deleted from claims 1 and 3, that encompassing SEQ ID NO:27, has been reinserted. This peptide is a single amino acid shorter than that disclosed by Merluzzi *et al.* Given use of the transitional phrase "consisting," applicants now submit that claims 32 and 33 are clearly novel over Merluzzi *et al.* Moreover, there is no motivation in Merluzzi *et al.* (or the other references for that matter), to generate a truncated version of SMAP29, and there certainly is no expectation of success in making and using such a truncation given the unpredictability associated with possible loss of function. Thus, claims 32 and 33 are non-obvious as well.

Claims 34-55 are dependent from claim 1, and merely set forth a more specific embodiment of that claim where each peptide "consists" of the remaining sequences. Since no art has been cited against these other sequences, applicants presume they are allowable.

V. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Please date stamp and return the enclosed postcard as evidence of receipt.

Respectfully submitted,

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Date: July 28, 2003

APPENDIX A: MARKED UP COPY OF CLAIMS

1. (Twice amended) An isolated antimicrobial peptide of [not more than 50] 12-37 residues, the peptide comprising an amino acid sequence selected from the group consisting of:

KNLRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 1),
KNIRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 6),
KNIRRIIRKIIHIIKKYG (SEQ ID NO: 7),
KNLRRIIRKIIHIIKKYG (SEQ ID NO: 8),
NLRRIIRKIIHIIKKY (SEQ ID NO 9),
NIRRIIRKIIHIIKKY (SEQ ID NO: 10),
LRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 11),
LRRIIRKIIHIIKK (SEQ ID NO: 12),
IRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 13),
IRRIIRKIIHIIKK (SEQ ID NO: 14),
LRRIIRKIIHIIK-NH_2 (SEQ ID NO: 15),
RRIIRKIIHIIKK-NH_2 (SEQ ID NO: 16),
RRIIRKIIHIIK-NH_2 (SEQ ID NO: 17),
GLRKRLRKFRNKIKEKLKKIG (SEQ ID NO: 19),
KRLRKFRNKIKEKLKKIG (SEQ ID NO: 20),
RKRLRKFRNKIKEKLKKIGQKI (SEQ ID NO: 21),
LRKFRNKIKEKLKKIGQKI (SEQ ID NO: 22),
LRKFRNKIKEKLKKIGQKIQG (SEQ ID NO: 23),
RKFRNKIKEKLKKIG (SEQ ID NO: 24),
KIKEKLKKIGQKIQG (SEQ ID NO: 25),
KIKEKLKKIGQKIQGLL (SEQ ID NO: 26),
[RGLRRLGRKIAHGVKKYGPTVLRIIRIA-NH_2 (SEQ ID NO: 27),] and
KNLRRIIRKIIHIIKKYGPTILRIIRIIG-NH_2 (SEQ ID NO: 28).

3. (Twice amended) A pharmaceutical composition comprising an antimicrobial peptide of [not more than 50] 12 to 37 residues, the peptide comprising an amino acid sequence selected from the group consisting of:

KNLRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 1),
KNIRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 6),
KNIRRIIRKIIHIIKKYG (SEQ ID NO: 7),
KNLRRIIRKIIHIIKKYG (SEQ ID NO: 8),
NLRRIIRKIIHIIKKY (SEQ ID NO 9),
NIRRIIRKIIHIIKKY (SEQ ID NO: 10),
LRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 11),
LRRIIRKIIHIIKK (SEQ ID NO: 12),
IRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 13),
IRRIIRKIIHIIKK (SEQ ID NO: 14),
LRRIIRKIIHIIK-NH_2 (SEQ ID NO: 15),
RRIIRKIIHIIKK-NH_2 (SEQ ID NO: 16),
RRIIRKIIHIIK-NH_2 (SEQ ID NO: 17),
GLRKRLRKFRNKIKEKLKKIG (SEQ ID NO: 19),
KRLRKFRNKIKEKLKKIG (SEQ ID NO: 20),
RKRLRKFRNKIKEKLKKIGQKI (SEQ ID NO: 21),
LRKFRNKIKEKLKKIGQKI (SEQ ID NO: 22),
LRKFRNKIKEKLKKIGQKIQG (SEQ ID NO: 23),
RKFRNKIKEKLKKIG (SEQ ID NO: 24),
KIKEKLKKIGQKIQG (SEQ ID NO: 25),
KIKEKLKKIGQKIQGLL (SEQ ID NO: 26),
[RGLRRLGRKIAHGVKKYGPTVLRIIRIA-NH_2 (SEQ ID NO: 27),] and
KNLRRIIRKIIHIIKKYGPTILRIIRIIG-NH_2 (SEQ ID NO: 28),
formulated in a pharmaceutically acceptable carrier.

32. (New) An antimicrobial peptide consisting of the sequence RGLRRLGRKIAHGVKKYGPTVLRIIRIA-NH_2 (SEQ ID NO: 27).

33. (New) A pharmaceutical composition comprising (a) an antimicrobial peptide consisting of the sequence RGLRRLGRKIAHGVKKYGPTVLRIIRIA-NH_2 (SEQ ID NO: 27), and (b) a pharmaceutically acceptable carrier.

34. (New) An antimicrobial peptide consisting of the sequence KNLRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 1).

35. (New) The antimicrobial peptide of claim 1, consisting of the sequence KNIRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 6).

36. (New) The antimicrobial peptide of claim 1, consisting of the sequence KNIRRIIRKIIHIIKKYG (SEQ ID NO: 7).

37. (New) The antimicrobial peptide of claim 1, consisting of the sequence KNLRRIIRKIIHIIKKYG (SEQ ID NO: 8).

38. (New) The antimicrobial peptide of claim 1, consisting of the sequence NLRRIIRKIIHIIKKY (SEQ ID NO 9).

39. (New) The antimicrobial peptide of claim 1, consisting of the sequence NIRRIIRKIIHIIKKY (SEQ ID NO: 10).

40. (New) The antimicrobial peptide of claim 1, consisting of the sequence LRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 11).

41. (New) The antimicrobial peptide of claim 1, consisting of the sequence LRRIIRKIIHIIKK (SEQ ID NO: 12).

42. (New) The antimicrobial peptide of claim 1, consisting of the sequence IRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 13).

43. (New) The antimicrobial peptide of claim 1, consisting of the sequence IRRIIRKIIHIIKK (SEQ ID NO: 14).

44. (New) The antimicrobial peptide of claim 1, consisting of the sequence LRRIIRKIIHIIK-NH_2 (SEQ ID NO: 15).

45. (New) The antimicrobial peptide of claim 1, consisting of the sequence RRIIRKIIHIIKK-NH_2 (SEQ ID NO: 16).

46. (New) The antimicrobial peptide of claim 1, consisting of the sequence RRIIRKIIHIIK-NH_2 (SEQ ID NO: 17).

47. (New) The antimicrobial peptide of claim 1, consisting of the sequence GLRKRLRKFRNKIKEKLKKIG (SEQ ID NO: 19).

48. (New) The antimicrobial peptide of claim 1, consisting of the sequence KRLRKFRNKIKEKLKKIG (SEQ ID NO: 20).

49. (New) The antimicrobial peptide of claim 1, consisting of the sequence RKRLRKFRNKIKEKLKKIGQKI (SEQ ID NO: 21).

50. (New) The antimicrobial peptide of claim 1, consisting of the sequence LRKFRNKIKEKLKKIGQKI (SEQ ID NO: 22).

51. (New) The antimicrobial peptide of claim 1, consisting of the sequence LRKFRNKIKEKLKKIGQKIQG (SEQ ID NO: 23).

52. (New) The antimicrobial peptide of claim 1, consisting of the sequence RKFRNKIKEKLKKIG (SEQ ID NO: 24).

53. (New) The antimicrobial peptide of claim 1, consisting of the sequence KIKEKLKKIGQKIQG (SEQ ID NO: 25).

54. (New) The antimicrobial peptide of claim 1, consisting of the sequence KIKEKLKKIGQKIQGLL (SEQ ID NO: 26).

55. (New) The antimicrobial peptide of claim 1, consisting of the sequence KNLRRIIRKIIHIIKKYGPTILRIIRIIG-NH_2 (SEQ ID NO: 28).

APPENDIX B: CLEAN COPY OF PENDING CLAIMS (UNOFFICIAL)

1. An isolated antimicrobial peptide of 14-37 residues, the peptide comprising an amino acid sequence selected from the group consisting of:

KNLRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 1),
KNIRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 6),
KNIRRIIRKIIHIIKKYG (SEQ ID NO: 7),
KNLRRIIRKIIHIIKKYG (SEQ ID NO: 8),
NLRRIIRKIIHIIKKY (SEQ ID NO 9),
NIRRIIRKIIHIIKKY (SEQ ID NO: 10),
LRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 11),
LRRIIRKIIHIIKK (SEQ ID NO: 12),
IRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 13),
IRRIIRKIIHIIKK (SEQ ID NO: 14),
LRRIIRKIIHIIK-NH_2 (SEQ ID NO: 15),
RRIIRKIIHIIKK-NH_2 (SEQ ID NO: 16),
RRIIRKIIHIIK-NH_2 (SEQ ID NO: 17),
GLRKRLRKFRNKIKEKLKKIG (SEQ ID NO: 19),
KRLRKFRNKIKEKLKKIG (SEQ ID NO: 20),
RKRLRKFRNKIKEKLKKIGQKI (SEQ ID NO: 21),
LRKFRNKIKEKLKKIGQKI (SEQ ID NO: 22),
LRKFRNKIKEKLKKIGQKIQG (SEQ ID NO: 23),
RKFRNKIKEKLKKIG (SEQ ID NO: 24),
KIKEKLKKIGQKIQG (SEQ ID NO: 25),
KIKEKLKKIGQKIQGLL (SEQ ID NO: 26), and
KNLRRIIRKIIHIIKKYGPTILRIIRIIG-NH2 (SEQ ID NO: 28).

3. A pharmaceutical composition comprising an antimicrobial peptide of 14 to 37 residues, the peptide comprising an amino acid sequence selected from the group consisting of:

KNLRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 1),
KNIRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 6),
KNIRRIIRKIIHIIKKYG (SEQ ID NO: 7),
KNLRRIIRKIIHIIKKYG (SEQ ID NO: 8),
NLRRIIRKIIHIIKKY (SEQ ID NO 9),
NIRRIIRKIIHIIKKY (SEQ ID NO: 10),
LRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 11),
LRRIIRKIIHIIKK (SEQ ID NO: 12),
IRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 13),
IRRIIRKIIHIIKK (SEQ ID NO: 14),
LRRIIRKIIHIIK-NH_2 (SEQ ID NO: 15),
RRIIRKIIHIIKK-NH_2 (SEQ ID NO: 16),
RRIIRKIIHIIK-NH_2 (SEQ ID NO: 17),
GLRKRLRKFRNKIKEKLKKIG (SEQ ID NO: 19),
KRLRKFRNKIKEKLKKIG (SEQ ID NO: 20),
RKRLRKFRNKIKEKLKKIGQKI (SEQ ID NO: 21),
LRKFRNKIKEKLKKIGQKI (SEQ ID NO: 22),
LRKFRNKIKEKLKKIGQKIQG (SEQ ID NO: 23),
RKFRNKIKEKLKKIG (SEQ ID NO: 24),
KIKEKLKKIGQKIQG (SEQ ID NO: 25),
KIKEKLKKIGQKIQGLL (SEQ ID NO: 26), and
KNLRRIIRKIIHIIKKYGPTILRIIRIIG-NH_2 (SEQ ID NO: 28),
formulated in a pharmaceutically acceptable carrier.

32. An antimicrobial peptide consisting of the sequence RGLRRLGRKIAHGVKKYGPTVLRIIRIA-NH_2 (SEQ ID NO: 27).

33. A pharmaceutical composition comprising (a) an antimicrobial peptide consisting of the sequence RGLRRLGRKIAHGVKKYGPTVLRIIRIA-NH_2 (SEQ ID NO: 27), and (b) a pharmaceutically acceptable carrier.

34. An antimicrobial peptide consisting of the sequence KNLRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 1).

35. The antimicrobial peptide of claim 1, consisting of the sequence KNIRRIIRKIIHIIKKYG-NH_2 (SEQ ID NO: 6).

36. The antimicrobial peptide of claim 1, consisting of the sequence KNIRRIIRKIIHIIKKYG (SEQ ID NO: 7).

37. The antimicrobial peptide of claim 1, consisting of the sequence KNLRRIIRKIIHIIKKYG (SEQ ID NO: 8).

38. The antimicrobial peptide of claim 1, consisting of the sequence NLRRIIRKIIHIIKKY (SEQ ID NO 9).

39. The antimicrobial peptide of claim 1, consisting of the sequence NIRRIIRKIIHIIKKY (SEQ ID NO: 10).

40. The antimicrobial peptide of claim 1, consisting of the sequence LRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 11).

41. The antimicrobial peptide of claim 1, consisting of the sequence LRRIIRKIIHIIKK (SEQ ID NO: 12).

42. The antimicrobial peptide of claim 1, consisting of the sequence IRRIIRKIIHIIKK-NH_2 (SEQ ID NO: 13).

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47. The antimicrobial peptide of claim 1, consisting of the sequence GLRKRLRKFRNKIKEKLKKIG (SEQ ID NO: 19).

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53. The antimicrobial peptide of claim 1, consisting of the sequence KIKEKLKKIGQKIQG (SEQ ID NO: 25).

54. The antimicrobial peptide of claim 1, consisting of the sequence KIKEKLKKIGQKIQGLL (SEQ ID NO: 26).

55. The antimicrobial peptide of claim 1, consisting of the sequence KNLRRIIRKIIHIIKKYGPTILRIIRIIG-NH_2 (SEQ ID NO: 28).